The opinion in support of the decision being entered today is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte
A. SATYANARAYAN NAIDU

Appeal 2006-3089
Application 09/980,062
Technology Center 1600

DECIDED: August 17, 2007

Before TONI R. SCHEINER, ERIC GRIMES, and RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge.*

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims directed to immobilized lactoferrin, an antimicrobial agent. The claims stand rejected as anticipated by, and obvious over the prior art. We have jurisdiction under 35 U.S.C. § 6(b).

BACKGROUND

> Lactoferrin (LF) is an iron-binding glycoprotein present in milk and various mammalian secretions (e.g. saliva, tears, mucus, and seminal fluids). Crystallographic studies of LF indicate a bilobate structure (N-terminus and C-terminus lobes) with one iron-binding site in each lobe. . . . Various laboratory studies have reported that the structural integrity of LF is critical for its antimicrobial effects against bacteria, fungi, protozoa, and viruses.
>
> However, the activity of LF, like the activity of most proteins, is highly dependent on the three-dimensional or tertiary structure of the protein. If the protein does not have the proper conformation its activity is diminished or lost. LF's instability limits its usefulness. . . .
>
> In fact, under certain conditions, when the LF molecule is degraded or denatured, cationic peptide fragments are generated . . . [which] exhibit a non-specific antimicrobial activity, making them absolutely unsuitable as an ingredient in a food product.

Spec. 7: 8-25.

> The present invention includes compositions of matter comprising a defined dispersion of lactoferrin (LF) immobilized on a naturally occurring substrate via the amino-terminus (N-terminus) region of the lactoferrin. Such substrates . . . attach to the LF peptide at the amino-terminus (N-terminus), leaving the carboxy-terminal (C-terminal) end of the LF peptide free to interact with microbes. The inventive compositions containing immobilized lactoferrin (herein also referred to as "*Im*-LF") are effective in treating a wide variety of microbes including bacteria, fungi, protozoa and viruses.

Id. at 7: 34 to 8: 5.

The Specification does not further define the term "immobilized," but does indicate that "[i]mmobilization neutralizes the cationic effect of LF peptide fragments, and eliminates the undesirable, non-specific cidal activity characteristic of lactoferrin" (*id.* at 11: 12-13).

According to the Specification, suitable substrates for immobilization include "polysaccharides, such as mucin, heparan-sulfates, carrageenan, and cellulose" (Spec. at 10: 35 to 11:1), especially galactose-rich polysaccharides (*id.* at 10: 23); "proteins, such as collagen, denatured collagen (gelatin), fibronectin, and casein" (*id.* at 10: 35-36); "nucleic acids and their nucleotides, such as deoxyribonucleic acid and adenosine triphosphate; and lipids such as triglycerides" (*id.* at 11: 1-2).

Further, according to the Specification, "LF is immobilized on the substrate using any suitable technique. For example, LF can be immobilized simply by mixing the LF with the . . . substrate in a suitable medium, such as deionized water" (Spec. at 11: 3-5).

In Example 1 of the Specification, "[a] mixture of *Im*-LF and native LF was prepared by mixing a solution of [galactose-rich polysaccharide] (1% wt/vol) in deionized water with LF (1% wt/vol), . . . (also in deionized water) in a 1:100 ratio. The mixture was kept at room temperature with gentle stirring for 90 minutes. The formation of *Im*-LF was confirmed by gel-filtration chromatography" (Spec. at 33: 4-8).

An antimicrobial assay was performed to determine the effects of the *Im*-LF/LF mixture, as compared to native LF, on the growth of *E. coli* serotype O157:H7. "Both the LF and [the] *Im*-LF/LF mixture reduced the growth of the *E. coli*." Incubation with 1% LF resulted in a 64% reduction

in growth compared with the control, while incubation with 1% *Im*-LF/LF mixture resulted in a 72% reduction compared with the control. No statistical analysis was provided, so it cannot be determined whether the difference in growth reduction between the two samples was statistically significant. "[T]he *Im*-LF/LF mixture in buffer solution totally inhibited [ ] growth" (Spec. 34: 1-14), but no data were provided for native LF in buffer solution.

DISCUSSION

Claim 1-49, 51, and 56-202 are pending. Claims 1, 2, 5, 11, 18-20, 22, 28, 31, 32, 38, 39, 86, 101-104, 106, 115-117, 119-124, 126-129, 131-138, 142-151, 153, 154, 157-159, 162-165, 171-173, 175, 176, 179-181, 184-187, 193-197, and 200-202 are rejected and on appeal. In addition, the status of claim 3 is unclear because it is listed as merely objected to in the Final Rejection mailed April 7, 2003, but it is rejected under 35 U.S.C. § 102(e) in the Final Rejection and the Answer. The remaining claims have either been allowed, or are merely objected to.

Claims 1, 18, 38, 102, and 149 are representative, and read as follows:

1. A composition of matter comprising a dispersion of isolated lactoferrin immobilized on a naturally occurring substrate not including gelatin via the N-terminus region of the lactoferrin.

18. A method for reducing the microbial contamination of a composition subject to microbial contamination by a microbe, comprising: treating the composition with a sufficient amount of isolated lactoferrin immobilized on a naturally occurring substrate not including gelatin via the N-terminus region of the lactoferrin to reduce microbial contamination.

38. The method in accordance with claim 18, wherein the concentration of lactoferrin on the surface of the composition subject to microbial contamination is from about 0.0001 to about 10 mg/sq. inch.

102. A composition of matter comprising a dispersion of isolated lactoferrin immobilized on a naturally occurring substrate not including gelatin via the N-terminus region of the lactoferrin; and at least one pharmaceutically acceptable carrier.

149. The method of claim 18, wherein said composition subject to microbial contamination is a human.

The claims stand rejected as follows:

I. Claims 1, 11, 18, 28, 31, 38, 39, 101, 102, 119-124, 126-129, 131, 132, 134, 142-148, 197, and 200 under 35 U.S.C. § 102(b) as anticipated by Kruzel '982.[1], [2]

II. Claims 149-151, 153, 164, 171-173, 175, 186, and 193-195 under 35 U.S.C. § 103(a) as unpatentable over Kruzel '982.

III. Claims 1-3, 5, 18-20, 22, 31, 32, 102-104, 106, 115, 119, 124, 137, 138, 142-150, 154, 164, and 165 under 35 U.S.C. § 102(e) as anticipated by Kruzel '469.[3]

IV. Claims 1, 2, 5, 18, 19, 22, 31, 101-103, 106, 115-117, 119-124, 126-129, 131-132, 134, 136, 142-151, 153, 164, 171-173, 175, 186, 193-197, and 200-202 under 35 U.S.C. § 102(b) as anticipated by Valenti '309.[4]

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[1] International Patent Application WO 91/13982 of Kruzel et al., published September 19, 1991.
[2] Withdrawn with respect to claims 2, 19, and 103 (Answer 2).
[3] U.S. Patent 6,066,469 to Kruzel et al., issued May 23, 2000.
[4] European Patent Application EP 0 753 309 A2 of Valenti et al, published January 15, 1997.

V. Claims 38 and 39 under 35 U.S.C. § 103(a) as unpatentable over Valenti '309.

VI. Claims 1, 2, 5, 18, 19, 22, 31, 32, 101-103, 106, 115, 119-124, 126-129, 131-136, 142-151, 153, 159, 162-165, 171-173, 175, 181, 184-187, 193-197, and 200-202 under 35 U.S.C. § 102(b) as anticipated by Valenti '308.[5]

VII. Claims 38 and 39 under 35 U.S.C. § 103(a) as unpatentable over Valenti '308.

VIII. Claims 102-104, 115-117, 119, 124, 127, 128, 137, 138, 142-148, 154, 157, 158, 171, 172, 176, 179, 180, 186, and 193-196 under 35 U.S.C. § 102(e) as anticipated by Gohlke.[6]

IX. Claims 86 and 120-122 under 35 U.S.C. § 112, second paragraph, as indefinite.

Appellant does not present separate arguments for any particular claim with respect to any one rejection, therefore, the claims subject to each rejection will stand or fall together. We select claims 1, 38, 102, and 149 as representative of the subject matter on appeal. 37 C.F.R. § 41.37(c)(1)(vii).

REJECTIONS OVER PRIOR ART

"[I]n an *ex parte* proceeding to obtain a patent, . . . the Patent Office has the initial burden of coming forward with some sort of evidence tending to disprove novelty." *See In re Wilder*, 429 F.2d 447, 450, 166 USPQ 545, 548 (CCPA 1970). "A claim is anticipated only if each and every element as

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[5] European Patent Application EP 0 753 308 A2 of Valenti et al., published January 15, 1997.
[6] U.S. Patent 6,475,511 to Gohlke et al., issued November 5, 2002.

set forth in the claim is found, either expressly or *inherently* described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). "'[I]t is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art. Additionally, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.'" *In re Best*, 562 F.2d 1252, 1254-55, 195 USPQ 430, 433 (CCPA 1977) (quoting *In re Swinehart*, 439 F.2d 210, 212-13, 169 USPQ 226, 229 (CCPA 1971)). That is, "when the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

In the present case, there is no dispute that none of the references cited as evidence of anticipation explicitly describes lactoferrin immobilized via its N-terminus region to a substrate. The issue raised by this appeal with respect to each of the prior art rejections, then, is whether the Examiner has provided a reasonable basis for shifting the burden to Appellant to establish that the claimed lactoferrin compositions are distinguishable from the prior art compositions; and if so, whether Appellant's burden has been met.

Kruzel '982

The Examiner rejected claims 1, 11, 18, 28, 31, 38, 39, 101, 102, 119-124, 126-129, 131, 132, 134, 142-148, 197, and 200 under 35 U.S.C. § 102(b) as anticipated by Kruzel '982 (Rejection "I").

As discussed above, Appellant does not argue the claims separately with respect to this ground of rejection. We select claim 1 as representative, and the remaining claims will stand or fall accordingly.

Kruzel '982 describes lactoferrin compositions, including antiseptic compositions comprising lactoferrin "in the form of a powder, solution, ointment, aerosol spray, or cream" (Kruzel '982 at 7: 30-34), "either alone or compounded with carriers such as, saline silica, talcum, stearic acid, its magnesium or calcium salt, polyethylene[ ]glycol, and fatty emulsions and suspensions" (*id.* at 8: 3-8). Kruzel '982 also teaches that the antiseptic compositions can "contain . . . preserving, stabilizing, wetting or emulsifying agents, solution promoters, salts . . . and/or buffers" (*id.* at 9: 17-21).

The Examiner, noting that "[b]uffers can be present in the antiseptic compositions" (Answer 4), contends that "lactoferrin in combination with stearic acid (which is a lipid . . .) . . . will be immobilized via its N-terminus to the stearic acid to the same extent claimed" (*id.*), because "the same components are present in the same defined dispersion" (*id.*).

As discussed above, the Specification teaches that suitable substrates include lipids (Spec. 11: 2); that lactoferrin may be in solution, either alone or in combination with carriers like stearic acid (a lipid); and that lactoferrin may be immobilized via its N-terminus "simply by mixing the LF with the . . . substrate in a suitable medium, such as deionized water" (*id.* at 11: 3-5).

(See also Spec. 33 describing the immobilization of LF on galactose-rich polysaccharide by mixing it with water). Thus, the Specification does not state that anything more than combining LF with a substrate in water is needed to achieve "lactoferrin immobilized on a naturally occurring substrate . . . via the N-terminus region of the lactoferrin" as recited by claim 1. We also find nothing in the Specification to indicate that stearic acid, a lipid, is not a suitable substrate.[7] Accordingly, we find that the Examiner has established a reasonable basis for believing that the prior art lactoferrin, in solution with stearic acid, is attached to, or immobilized on, stearic acid via the N-terminus of lactoferrin, and the burden is properly shifted to Appellant to show otherwise.

Appellant relies on "factual evidence, in the form of the declaration of Dr. Andrew [R.] Barron,"[8] to establish that Kruzel '982 does not "inherently disclose[ ] the formation of lactoferrin immobilized on a naturally occurring substrate via the lactoferrin's N-terminus region" (Br. 12). Dr. Barron asserts that "the mere presence in a mixture of LF and stearic acid or any of the other naturally occurring carriers or diluents taught in . . . [Kruzel] '982 would not inherently result in the LF becoming attached via its N-terminus on a substrate" (Decl. ¶ 19), and "[m]erely compounding solid LF with other solids, such as stearic acid, will not provide an environment suitable to cause

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[7] We note that the Examiner has previously asserted, and it has not been disputed by Appellant, that stearic acid has a negatively charged carboxyl group (Final Rejection, dated April 7, 2005, at 12).

[8] Declaration of Dr. Andrew R. Barron, dated July 26, 2004, submitted under the provisions of 37 C.F.R. § 1.132 (hereinafter "Decl.").

the LF to become attached to the other solid via LF's N-terminus region" (*id.* at ¶ 20).

Nevertheless, as discussed above, Kruzel '982 describes more than just compounding solid lactoferrin with other solids. Kruzel '982 also describes antiseptic compositions comprising lactoferrin in solution, "either alone or compounded with carriers such as . . . stearic acid, its magnesium or calcium salt" (Kruzel '982 at 8: 3-6).

Inasmuch as Kruzel describes lactoferrin and stearic acid in solution, and the Specification teaches that "LF can be immobilized simply by mixing the LF with the . . . substrate in a suitable medium, such as deionized water" (Spec. at 11: 3-5), we are not persuaded by Dr. Barron's assertions regarding solid compounding.

Nor are we persuaded by Dr. Barron's assertion that "[s]tearic acid with a molecular weight of only 284.47 is not a substrate" and "LF could not become immobilized on such a small molecule" (Decl. ¶ 17) "as the term is to be understood in the context of the instant specification and claims" (Br. 21-22). The Specification makes no mention of size in describing suitable substrates for immobilizing lactoferrin, and in fact mentions nucleotides (e.g., adenosine triphosphate), which are considerably smaller than lactoferrin, as suitable substrates.

Finally, while acknowledging that Dr. Barron's declaration is inconsistent with the Specification on the issue of substrate size, Appellant argues that "[w]hat is wrong . . . is not applicant's argument, as supported by Dr. Barron's declaration. Instead, what was wrong was the original inclusion of lipids, such as stearic acid, among the examples of suitable

substrates . . . LF could not become immobilized on such a small molecule" (Br. 22).

Nevertheless, this is not a matter of right or wrong, it is a matter of interpretation based on the Specification. The term "substrate" is defined in the Specification in functional terms, and by inclusive examples. As discussed above, the Specification teaches that suitable substrates for immobilizing lactoferrin are compounds that "attach to the LF peptide at the amino-terminus (N-terminus), leaving the carboxy-terminal (C-terminal) end of the LF peptide free to interact with microbes" (Spec. 8: 1-3), and the list of examples of suitable substrates explicitly includes compounds as small as adenosine triphosphate. Dr. Barron has not explained why his more restrictive interpretation of "substrate" should take precedence over the way the term is interpreted based on substrates asserted to be suitable in the Specification.

We find that the Examiner has established a reasonable basis for believing that the prior art compositions meet all the limitations of claim 1, properly shifting the burden to Appellant to show otherwise. We further find that Appellant has not adequately discharged the burden of rebuttal, by argument or evidence. The rejection of claim 1 as anticipated by Kruzel '982 is affirmed, and claims 11, 18, 28, 31, 38, 39, 101, 102, 119-124, 126-129, 131, 132, 134, 142-148, 197, and 200 fall accordingly.

The Examiner rejected claims 149-151, 153, 164, 171-173, 175, 186, and 193-195 under 35 U.S.C. § 103(a) as unpatentable over Kruzel '982 (Rejection "II").

Appellant argues only that the claimed invention would not have been obvious over Kruzel '982, because the reference does not teach and "would not have suggested immobilizing LF on a naturally occurring substrate via its N-terminus region" (Br. 23).

This argument is not persuasive as we have already found that the Examiner has established a reasonable basis for believing that Kruzel '982 describes lactoferrin immobilized on a substrate via its N-terminus region, which Appellant has not adequately rebutted by argument or evidence.

The rejection of claims 149-151, 153, 164, 171-173, 175, 186, and 193-195 as unpatentable over Kruzel '982 is affirmed.

Kruzel '469

Claims 1-3, 5, 18-20, 22, 31, 32, 102-104, 106, 115, 119, 124, 137, 138, 142-150, 154, 164, and 165 stand rejected under 35 U.S.C. § 102(e) as anticipated by Kruzel '469 (Rejection "III").

Appellant does not argue the claims separately with respect to this ground of rejection. We select claim 1 as representative, and the remaining claims will stand or fall accordingly.

Kruzel '469 describes nutritional supplements comprising "liquids containing [ ] lactoferrin together with adjuvants or diluents, such as . . . cellulose, . . . starch, . . . geslatin [sic], tragacanth, methyl-cellulose, [and] sodium carboxymethylcellulose" (Kruzel '469 col. 8, ll. 51-56). The supplements can also contain buffers (*id.* at col. 9, l. 36).

The Examiner contends that "inherently the lactoferrin in the nutritional supplements . . . will be immobilized via its N-terminus to the carriers or diluents to the same extent claimed" (Answer 8), "[b]ecause the same components are present in the same defined dispersion" (*id.*).

Appellant again relies on the Declaration of Dr. Andrew R. Barron to establish that Kruzel '469 does not describe immobilized lactoferrin (Br. 12). Dr. Barron asserts that "[m]erely compounding LF with other solids, such as by cold-pressing two or more solids, will not provide an environment suitable to cause the LF to become immobilized via its N-terminus region" (Decl. ¶ 38), and "the mere presence in a mixture of LF and any of the adjuvants or diluents, such [as] the solids cellulose, starch, tragacanth, or sodium carboxymethylcellulose would not inherently result in immobilization of the LF via its N-terminus" (*id.* at ¶ 37). Finally, Dr. Barron asserts that "[c]ellulose and starch do not carry any charges. As a result, neither cellulose nor starch contains a region that will attach LF's positively charged N-terminus region" (*id.* at ¶ 36).

Nevertheless, as discussed above, Kruzel '469 describes more than just solid lactoferrin compounded with other solids. Kruzel '469 also describes "liquids containing the lactoferrin together with adjuvants or diluents, such as . . . cellulose, . . . starch, . . . geslatin [sic], tragacanth, methyl-cellulose, [or] sodium carboxymethylcellulose" (Kruzel '469, col. 8, ll. 51-56). Moreover, the present Specification explicitly lists cellulose as a suitable substrate (Spec. 10: 20 and 11: 1).

Inasmuch as Kruzel '469 describes a liquid containing lactoferrin and cellulose, and the Specification teaches that "LF can be immobilized simply by mixing the LF with the . . . substrate in a suitable medium, such as deionized water" (Spec. at 11: 3-5), we are not persuaded by Dr. Barron's assertions that Kruzel '469 does not describe lactoferrin immobilized via its N-terminus to cellulose.

We find that the Examiner has established a reasonable basis for believing that the compositions described by Kruzel '469 meet all the limitations of claim 1, properly shifting the burden to Appellant to show otherwise. We further find that Appellant has not adequately discharged the burden of rebuttal, by argument or evidence. The rejection of claim 1 as anticipated by Kruzel '469 is affirmed, and claims 2, 3, 5, 18-20, 22, 31, 32, 102-104, 106, 115, 119, 124, 137, 138, 142-150, 154, 164, and 165 under 35 U.S.C. § 102(e) fall accordingly.

Valenti '309

Claims 1, 2, 5, 18, 19, 22, 31, 101-103, 106, 115-117, 119-124, 126-129, 131-132, 134, 136, 142-151, 153, 164, 171-173, 175, 186, 193-197, and 200-202 stand rejected under 35 U.S.C. § 102(b) as anticipated by Valenti '309 (Rejection "IV").

Appellant does not argue the claims separately with respect to this ground of rejection. We select claim 1 as representative, and the remaining claims will stand or fall accordingly.

Valenti '309 describes solutions of lactoferrin and desferrioxamine methanesulfonate, "in solvents acceptable for pharmaceutical use, in

particular water or hydroalcholic [sic] solvents such as water-ethanol mixtures" (Valenti '309 4: 16-22). The Examiner notes that "[t]he compositions are in the form of ointments, creams, [and] gels" (Answer 5), and comprise "lactoferrin and carriers such as paraffin oil and Vaseline . . . , xantan gum and corn starch (which are polysaccharides), and lecithin (which is an emulsifier" (*id.*). Example 7 of Valenti '309, e.g., describes a gel containing lactoferrin, xantan gum, lecithin and distilled water.

The Examiner argues that "inherently the lactoferrin in the composition of . . . [Valenti] '309 will be immobilized via its N-terminus . . . to the same extent claimed" (Answer 6).

Appellant, again relying on the declaration of Dr. Barron, argues that "[l]ecithin is a low molecular weight compound" and "LF could not become immobilized on such a small molecule" (Decl. ¶ 27). Moreover, "[x]antan gum and cornstarch do not carry any charges. As a result, neither xantan gum nor cornstarch contains a region that will attach LF's positively charged N-terminus region" (Decl. ¶ 26).

These arguments are not persuasive. As discussed above, the Specification makes no mention of size in describing suitable substrates for immobilizing lactoferrin, and in fact mentions nucleotides (e.g., adenosine triphosphate), which are considerably smaller than lactoferrin, as suitable substrates. In addition, also as discussed above, the Specification explicitly lists cellulose as a suitable substrate (Spec. 10: 20 and 11: 1), even though cellulose carries no charge.

We find that the Examiner has established a reasonable basis for believing that the compositions described by Valenti '309 meet all the

limitations of claim 1, properly shifting the burden to Appellant to show otherwise. We further find that Appellant has not adequately discharged the burden of rebuttal, by argument or evidence. The rejection of claim 1 as anticipated by Valenti '309 is affirmed, and claims 2, 5, 18, 19, 22, 31, 101-103, 106, 115-117, 119-124, 126-129, 131-132, 134, 136, 142-151, 153, 164, 171-173, 175, 186, 193-197, and 200-202 fall accordingly.

Claims 38 and 39 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Valenti '309 (Rejection "V").

Appellant argues only that the claimed invention would not have been obvious over Valenti '309 because the reference does not teach and "would not have suggested immobilizing LF on a naturally occurring substrate via its N-terminus region" (Br. 25).

This argument is not persuasive as we have already found that the Examiner has established a reasonable basis for believing that Valenti '309 describes lactoferrin immobilized on a substrate via its N-terminus region, which Appellant has not adequately rebutted by argument or evidence. The rejection of claims 38 and 39 over Valenti '309 is affirmed.

Valenti '308

Claims 1, 2, 5, 18, 19, 22, 31, 32, 101-103, 106, 115, 119-124, 126-129, 131-136, 142-151, 153, 159, 162-165, 171-173, 175, 181, 184-187, 193-197, and 200-202 stand rejected under 35 U.S.C. § 102(b) as anticipated by Valenti '308 (Rejection "VI").

Appellant does not argue the claims separately with respect to this ground of rejection. We select claim 1 as representative, and the remaining claims will stand or fall accordingly.

Valenti '308 describes preparations of lactoferrin "in solvents acce[p]table for pharmaceutical use, in particular water or hydro-alcoholic solvents such as water-ethanol mixtures" (Valenti '308 3: 34-36). The Examiner notes that "[t]he compositions are in the form of gargles, aqueous solutions, [and] chewing gum[s]" (Answer 7), and comprise "lactoferrin and peppermint oil, gum base and corn starch (which are polysaccharides), glucose, and additional antibiotic compounds" (*id.*). Example 5 of Valenti '308, e.g., describes a gargle containing lactoferrin, peppermint oil and purified water, while Example 7 describes a chewing gum comprising lactoferrin, gum base and peppermint oil.

The Examiner argues that "inherently the lactoferrin in the composition of . . . [Valenti] '308 will be immobilized via its N-terminus . . . to the same extent claimed" (Answer 7).

Appellant, again relying on the declaration of Dr. Barron, argues that "[p]eppermint oil is a low molecular weight compound, not a substrate" and "LF could not become immobilized on such a small molecule" (Decl. ¶ 30). Moreover, "[p]eppermint oil, gum base and cornstarch do not carry any charges. As a result, neither gum base nor cornstarch contains a region that will attach LF's positively charged N-terminus region" (Decl. ¶ 31).

These arguments are not persuasive. Again, the Specification makes no mention of size in describing suitable substrates for immobilizing lactoferrin, and in fact mentions nucleotides (e.g., adenosine triphosphate),

which are considerably smaller than lactoferrin, as suitable substrates. In addition, also as discussed above, the Specification explicitly lists cellulose as a suitable substrate (Spec. 10: 20 and 11: 1), even though cellulose carries no charge.

We find that the Examiner has established a reasonable basis for believing that the compositions described by Valenti '308 meet all the limitations of claim 1, properly shifting the burden to Appellant to show otherwise. We further find that Appellant has not adequately discharged the burden of rebuttal, by argument or evidence. The rejection of claim 1 as anticipated by Valenti '309 is affirmed, and claims 2, 5, 18, 19, 22, 31, 32, 101-103, 106, 115, 119-124, 126-129, 131-136, 142-151, 153, 159, 162-165, 171-173, 175, 181, 184-187, 193-197, and 200-202 fall accordingly.

Claims 38 and 39 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Valenti '308 (Rejection "VII").

Appellant argues only that the claimed invention would not have been obvious over Valenti '308 because the reference does not teach and "would not have suggested immobilizing LF on a naturally occurring substrate via its N-terminus region" (Br. 27).

This argument is not persuasive as we have already found that the Examiner has established a reasonable basis for believing that Valenti '308 describes lactoferrin immobilized on a substrate via its N-terminus region, which Appellant has not adequately rebutted by argument or evidence. The rejection of claims 38 and 39 over Valenti '308 is affirmed.

Gohlke

Claims 102-104, 115-117, 119, 124, 127, 128, 137, 138, 142-148, 154, 157, 158, 171, 172, 176, 179, 180, 186, and 193-196 stand rejected under 35 U.S.C. § 102(e) as anticipated by Gohlke (Rejection "VIII").

We will reverse this rejection.

Gohlke describes combining powdered lactoferrin with powdered colostrum, and cold pressing the mixture into a lozenge. The Examiner contends that "inherently the lactoferrin in the lozenges of Gohlke [ ] will be immobilized . . . to the proteins, polysaccharides, and lipids which are present" in the colostrum "[b]ecause the same components are present in the same compositions" (Answer 9).

Appellant, again relying on Dr. Barron's declaration, argues that "immobilized LF will not be formed, if LF is simply admixed with another solid" (Br. 19). As explained by Dr. Barron, "mixing LF with colostrum (and modified pectin) and cold pressing will not provide an environment suitable to cause the LF to become attached to colostrums or modified pectin via LF's N-terminus region" (Decl. ¶ 14).

Appellant has the better argument. The Examiner has pointed to no evidence of record to support his position that cold-pressing lactoferrin and a substrate would result in immobilization, while Appellant has provided declaratory evidence that it would not. Appellant's evidence is sufficient to rebut the rejection based on Gohlke. The rejection of claims 102-104, 115-117, 119, 124, 127, 128, 137, 138, 142-148, 154, 157, 158, 171, 172, 176, 179, 180, 186, and 193-196 is reversed.

INDEFINITENESS

The Examiner rejected claims 86 and 120-122 under 35 U.S.C. § 112, second paragraph, as indefinite (Rejection "IX").

Appellant does not address this rejection in the Brief, or the Reply Brief.

Accordingly, the rejection of claims 86 and 120-122 as indefinite is affirmed.

SUMMARY

Rejections I, IV, and VI under 35 U.S.C. § 102(b) are affirmed.

Rejections II, V, and VII under 35 U.S.C. § 103(a) are affirmed.

Rejection III under 35 U.S.C. § 102(e) is affirmed.

Rejection VIII under 35 U.S.C. § 102(e) is reversed.

Rejection IX under 35 U.S.C. § 112, second paragraph is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

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